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PTO/SB/21 (09-04)

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JW**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

16

Application Number

10/091,172

Filing Date

3/4/2002

First Named Inventor

Juan I. Perez

Art Unit

3738

Examiner Name

Thomas C. Barrett

Attorney Docket Number

ENDOV-55674

**ENCLOSURES (Check all that apply)**

Fee Transmittal Form



Fee Attached



Amendment / Reply



After Final



Affidavits/declaration(s)



Extension of Time Request



Express Abandonment Request



Information Disclosure Statement



Certified Copy of Priority Document(s)

Response to Missing Parts/  
Incomplete ApplicationReply to Missing Parts under  
37 CFR 1.52 or 1.53

Drawing(s)



Licensing-related Papers



Petition

Petition to Convert to a  
Provisional ApplicationPower of Attorney, Revocation  
Change of Correspondence Address

Terminal Disclaimer



Request for Refund



CD, Number of CD(s) \_\_\_\_\_



Landscape Table on CD

After Allowance Communication  
to TCAppeal Communication to Board  
of Appeals and InterferencesAppeal Communication to TC  
(Appeal Notice, Brief, Reply Brief)

Proprietary Information



Status Letter

Other Enclosure(s) (please  
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**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name

FULWIDER PATTON LLP

Signature

Printed name

John V. Hanley

Date

6/20/2006

Reg. No.

38,171

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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/17 (01-06)

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**FEE TRANSMITTAL  
for FY 2006**☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT (\$)** \$500.00**Complete if Known**

Application Number	10/091,172
Filing Date	3/4/2002
First Named Inventor	Juan I. Perez
Examiner Name	Crystal M. Gilpin
Art Unit	3738
Attorney Docket No.	ENDOV-55674

**METHOD OF PAYMENT** (check all that apply)☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_☒ Deposit Account Deposit Account Number: 06-2425 Deposit Account Name: Fulwider Patton LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or any underpayments of fee(s) under 37 CFR 1.16 and 1.17☒ Credit any overpayments**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION** (All the fees below are due upon filing or may be subject to a surcharge.)**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid(\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
_____ - 20 or HP = _____	x _____	\$50.00	= \$0.00

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
_____ - 3 or HP = _____	x _____	\$200.00	= \$0.00

HP = highest number of independent claims paid for, if greater than 3.

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listing under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____ - 100 = _____	_____ / 50	_____ (round up to a whole number) x	\$250.00	= \$0.00

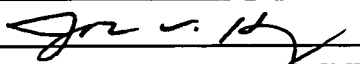
**4. OTHER FEE(S)**

Non-English specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Appellant's Brief

\$500.00

**SUBMITTED BY**

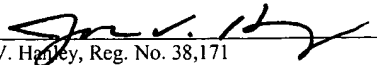
Signature		Registration No. (Attorney/Agent)	38,171	Telephone	310-824-5555
Name (Print/Type)	John V. Hanley			Date	6/20/2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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John V. Hanley, Reg. No. 38,171

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the application of

Inventor: Juan I. Perez, et al.

Serial No. 10/091,172

Filed: March 4, 2002

For: STAGED ENDOVASCULAR GRAFT  
DELIVERY SYSTEM

Examiner: Thomas Barrett

Group Art Unit: 3738

Date: June 20, 2006

APPELLANT'S BRIEF (CFR § 1.192)

MS: Appeal Brief Patents  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Appellant's Brief is being filed in response to the final Office action dated January 31, 2006. The fees required under § 1.17 were submitted on May 1, 2006 with the Notice of Appeal. The fee associated with this paper is transmitted herewith. In the event additional fees are required, authorization is hereby provided to charge our Deposit Account No. 06-2425 any fees due in connection with this paper.

This brief contains items under the following headings, and in the order set forth below:

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- I. REAL PARTY IN INTEREST
- II. RELATED APPEALS AND INTERFERENCES
- III. STATUS OF CLAIMS
- IV. STATUS OF AMENDMENTS
- V. SUMMARY OF CLAIMED INVENTION
- VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL
- VII. ARGUMENT
- VIII. CLAIMS APPENDIX

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is the following party: EndoVascular Technologies, Inc., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a wholly-owned subsidiary of Guidant Corporation which is a wholly-owned subsidiary of Boston Scientific Corporation, 1 Boston Scientific Place, Natick, MA 01760.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that is believed there are no such appeals or interferences known to the applicant.

III. STATUS OF CLAIMS

The status of the claims in this application are:

A. Total Number of Claims in the Application

The claims in the application are: Claims 1-25

B. Status of All of the Claims

Each of pending claims 1-6, 8, 9, 12, 15, 17-19, 21, 24 and 25 stand as finally rejected under 35 U.S.C. § 102(b). Additionally, claims 1-10, 12-22, 24 and 25 stand as finally rejected under § 103(a). Claims 11 and 23 were objected to as being dependent upon a rejected claim.

C. Claims on Appeals

The claims on appeal are each of pending claims 1-10, 12-22, 24 and 25.

IV. STATUS OF AMENDMENTS

On January 31, 2006, claims 1-6, 8, 9, 12, 15, 17-19, 21, 24 and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by Poncet (U.S. 5,833,694; Exhibit A). Additionally, claims 1-9, 12-22, 24 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over McDonald et al. (U.S. 6,090,136; Exhibit B) in view of Staehle et al. (U.S. 6,132,458; Exhibit C). Claim 10 was rejected under § 103(a) in view of Poncet.

V. SUMMARY OF CLAIMED INVENTION

As set forth in the pending independent claims, the presently claimed invention relates to a system or a method involving a system including a sheath assembly and a loading capsule (See Summary of the Invention, page 7, line 5 et seq.). An initial or a first treatment component in the form of an implant or a graft as well as subsequent treatment components in the form of implants or grafts are received by the system and advanced thereby to a treatment site (See also original claims).

In one particular aspect, the system 110 includes a loading capsule 112 having a superior end that is configured to mate with an inferior end of the introducer sheath 17, (See page 20, line 10 et seq.). In this way, a method of delivering initial and then successive treatment components to a treatment site is provided.

## VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-6, 8, 9, 12, 15, 17-19, 21, 24 and 25 were improperly rejected under 35 U.S.C. § 102(b) as being anticipated by Poncet. Additionally, whether claims 1-9, 12-22, 24 and 25 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over McDonald et al. in view of Staehle et al. and whether claim 10 was improperly rejected under § 103(a) in view of Poncet.

## VII. ARGUMENT

### A. § 102(b) Rejection

As stated, claims 1-6, 8, 9, 12, 15, 17-19, 21, 24 and 25 were rejected under § 102(b) as being anticipated by Poncet. It is respectfully submitted, however, that Poncet does not teach each and every limitation recited in the rejected claims as is required under 35 U.S.C. § 102(b).

In rejecting the claims in view of the Poncet reference, the Examiner drew the Applicants attention to Col. 8, lns. 4-15 and figures 12 and 13 of that reference. However, these sections of the Poncet patent upon which the Examiner relies does not teach the combination of the first sheath and the loading capsule recited in the pending claims.

Each of independent claims 1 and 18 recite a system including a loading capsule including a superior end and a sheath including an inferior end, the superior and inferior ends being configured to mate with each other. The terms superior and inferior are defined in the

present application at page 8, line 12 et seq. Significantly, FIGS. 12 and 13 of Poncet disclose a sheath 10 including an enlarged portion 16 at its distal or superior end. Stents are loaded into distal or superior end of the sheath 10 by employing a stent cartridge 130 with an open end 134 formed at its superior or distal end and which is designed to mate with the enlarged portion 16 of the sheath 10.

Accordingly, rather than teaching the recited loading capsule with a superior end that mates with an inferior end of a sheath, the Poncet reference actually teaches mating superior ends of two devices. This difference is significant since one intent of the present invention is to provide a sheath which includes a superior end which remains in vasculature while subsequent treatment devices are inserted within the inferior end of the sheath to subsequently be advanced through the sheath to its superior end.

Therefore, it is submitted that the Poncet patent does not teach each and every limitation recited in independent claims 1 and 18 or their respective dependent claims, namely claims 2-6, 8, 9, 12, 15, 17, 24 and claims 19, 21 and 25. As such, it is respectfully submitted that these claims were improperly rejected under § 102(b).

B. § 103(a) Rejection

Claims 1-9, 12, 22, 24 and 25 were rejected under § 103(a) over McDonald et al. in view of Staehle et al. and claim 10 was rejected under § 103(a) over Poncet.

It is respectfully submitted, however, that none of the cited prior art references teach the subject matter recited in independent claims 1, 18 and 22 or their respective dependent claims. Significantly, none of the cited art, either alone or in combination, teach a system including a first sheath configured to receive a subsequent treatment or graft component after the sheath is placed within vasculature and a loading capsule including a superior end that is configured to mate with an inferior end of the first sheath.

A tenet which is highly significant to the prosecution of the present application is set forth in MPEP Section 2143.03. That is, to "establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." In re Rozka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

It is also significant to the present application that MPEP 2145 states that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine references teachings. It is additionally to be noted that MPEP 2143.01 states that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination" and that "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because references relied upon teach all of the aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objection reason to combine the teachings of the references." Further, the MPEP states that "The level of skill in the art cannot be relied upon to provide the suggestion to combine the references."

In rejecting the claims under § 103(a) over McDonald et al. in view of Staehle et al., the Examiner stated that "It would have been obvious to one of ordinary skill in the art to combine the teachings...the motivation to combine being the capsule of Staehle et al. is an 'easy and effective loading device' " (Col. 2, lines 24-26). It is respectfully submitted, however, that the motivation upon which the Examiner has relied to combine the teachings does not satisfy the guidelines provided by the MPEP as set forth above.

That is, simply because the Staehle et al. patent states that there is a need for "an effective loading device" (which, incidentally, is a statement made in the Background of the Invention of Staehle et al. and one which is not made respecting nor necessarily attributable to the Staehle et al. disclosed device) does not support modifying the teachings of McDonald et al. as suggested by the Examiner. Significantly, the device 10 of Staehle et al. includes a funnel 19 intended to reduce the profile of a stent while advancing the stent within a deployment tool 12. However, there is nothing in the cited references to suggest that such an approach would even be workable with the rolled stent 13 disclosed in McDonald et al. In fact, one can imagine the rolled stent 13 of McDonald et al. becoming stuck within the funnel 19 structure of the Staehle et al. device 10 if an attempt was made to advance it therethrough. Accordingly, it is submitted that there is no basis for concluding that one of ordinary skill in the art would have modified the approach taught by McDonald et al. to include the device 10 of Staehle et al. Thus, it is respectfully submitted that a sufficient objection reason has not been provided to combine the teachings of McDonald et al. and Staehle et al. and as such, a *prima facie* case of obviousness has not been established to reject the claims.

Moreover, even if the combination was proper under the MPEP, it is significant that both the McDonald et al. and the Staehle et al. references are lacking in the teaching of the recited sheath and loading capsule. That is, the cited references also do not meet the limitations of independent apparatus claims 1 and 18 or independent method claim 22 which require among other things, mating or a mating arrangement between a superior terminal end of a loading capsule with an inferior end of sheath.

As the Examiner noted, the McDonald et al. patent does not teach the recited loading capsule. Moreover, as established above, there is no suggestion or teaching that the Staehle et al.

structure would work with the McDonald et al. stent. Further, there is no indication in Staehle et al. that the disclosed structure it is intended to include a superior end configured to mate with an inferior end of a sheath. Therefore, the combination of McDonald et al. and Staehle et al. fail to meet the limitations recited in claims 1-9, 12-22, 24 and 25.

Also, as set forth above in the section concerning the § 102 rejection, the Poncet patent completely lacks the teaching of a mating arrangement between a superior end of a loading capsule and an inferior end of a sheath. Thus, the § 103(a) rejection of claim 10 over Poncet necessarily must fall short since claim 10 further limits claim 1.

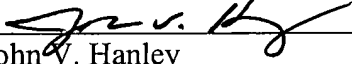
Accordingly, it is submitted that the § 103(a) rejections of the claim 10 as well as claims 1-9, 12-22, 24 and 25 were improper.

CONCLUSION

For all the reasons stated above, Applicant respectfully submits that the Examiner has erred in rejecting claims 1-10, 12-22, 24 and 25. It is respectfully requested that the Board reverse the rejection of the claims 1-10, 12-22, 24 and 25 and pass each of pending claims 1-25 to issue.

Respectfully submitted,

FULWIDER PATTON LLP

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## VIII. CLAIMS

Claim 1 (previously presented): A system for treating vasculature at a repair site, comprising:

a first treatment component;

a first sheath having the first treatment component and configured to receive a subsequent treatment component after the first sheath is placed within the vasculature and the first treatment component is deployed, the first sheath having an inferior end and a length sufficient to extend to a repair site within the vasculature; and

a loading capsule configured to receive a subsequent treatment component, wherein the loading capsule includes a superior terminal end that is configured to mate with the inferior end of the first sheath.

Claim 2 (previously presented): The system of claim 1, further comprising a plurality of subsequent treatment components.

Claim 3 (previously presented): The system of claim 2, wherein the initial sheath is retracted to deploy treatment components at a repair site.

Claim 4 (previously presented): The system of claim 2, wherein the first sheath is configured to retain the plurality of subsequent treatment components in a compressed configuration.

Claim 5 (previously presented): The system of claim 1, wherein the first treatment component is self-expanding.

Claim 6 (previously presented): The system of claim 5, wherein the loading capsule is configured to releasably retain the first treatment component in a compressed configuration.

Claim 7 (previously presented): The system of claim 1, further comprising a guidewire.

Claim 8 (previously presented): The system of claim 1, further comprising a pusher assembly.

Claim 9 (previously presented): The system of claim 8, wherein the pusher assembly is configured to simultaneously engage a plurality of treatment components.

Claim 10 (previously presented): The system of claim 8, the pusher assembly further comprising a tapered flexible tip.

Claim 11 (previously presented): The system of claim 8, the pusher assembly being adapted to accomplish cloverfolding of the first treatment component.

Claim 12 (previously presented): The system of claim 8, the pusher assembly includes an inner tube.

Claim 13 (previously presented): The system of claim 12, the inner tube including an inferior end, a superior end and an exit notch.

Claim 14 (previously presented): The system of claim 13, the inner tube further comprising a guidewire passageway between the superior end and exit notch.

Claim 15 (previously presented): The system of claim 1, wherein the loading capsule and first sheath have approximately equal outer profiles at a mating juncture therebetween.

Claim 16 (previously presented): The system of claim 8, wherein the pusher assembly is configured to advance treatment components substantially the length of the first sheath.

Claim 17 (previously presented): The system of claim 1, wherein the first sheath remains within vasculature during the delivery of multiple treatment components at a repair site.

Claim 18 (previously presented): A system for treating vasculature at a repair site, comprising:

a plurality of endovascular graft components;

a pusher assembly configured to releasably receive each of the plurality of endovascular graft components;

a loading capsule assembly configured to receive the pusher assembly and including a superior terminal end; and

an introducer sheath having an inferior end configured to mate with the superior terminal end of the loading capsule assembly and to facilitate the transfer of the plurality of endovascular graft components from the loading capsule assembly.

Claim 19 (previously presented): The system of claim 18, wherein the introducer sheath and the loading capsule have substantially the same outer profiles at a mating juncture therebetween.

Claim 20 (previously presented): The system of claim 18, further comprising a guidewire.

Claim 21 (previously presented): The system of claim 18, wherein each of the plurality of endovascular grafts are self-expanding.

Claim 22 (previously presented): A method for treating vasculature at a repair site using a system including an initial introducer sheath having an inferior end and configured to receive an endovascular graft and configured to receive subsequent endovascular graft components carried by a loading capsule with a superior terminal end after placement of the introducer sheath within vasculature, the introducer sheath extending to the repair site, comprising:

gaining access to vasculature;

inserting initial introducer sheath loaded with the endovascular graft component within vasculature and positioning a superior end of the initial introducer sheath at the repair site;

retracting the initial introducer sheath to deploy the endovascular graft component;

mating the superior terminal end of the loading capsule with the inferior end of the initial introducer sheath;

inserting a subsequent endovascular graft component in the inferior end of the initial introducer sheath;

advancing the subsequent endovascular graft component within the initial introducer sheath; and

deploying the subsequent endovascular graft component at the repair site by retracting the initial introducer sheath.

Claim 23 (previously presented): The method of claim 22, wherein the system includes a pusher assembly and a loading capsule assembly, comprising:

configuring a plurality of subsequent endovascular graft components on the pusher assembly; and

advancing the pusher assembly first through the loading capsule and then into the introducer sheath.

Claim 24 (previously presented): The system of claim 1, further comprising:

a first fitting, the first fitting attached to the superior terminal end of the loading capsule;  
and

a second fitting, the second fitting attached to the inferior end of the first sheath;

wherein the first fitting and second fitting releasably connect to each other.

Claim 25 (previously presented): The system of claim 18, further comprising:  
a first fitting, the first fitting attached to the superior terminal end of the loading capsule;  
and  
a second fitting, the second fitting attached to the inferior end of the first sheath;  
wherein the first fitting and second fitting releasably connect to each other.